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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,591	04/02/2004	Matti Sallberg	TRIEP.23AUS2C1	4899
20995	7590	11/17/2005	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP			LI, BAO Q	
2040 MAIN STREET			ART UNIT	
FOURTEENTH FLOOR			PAPER NUMBER	
IRVINE, CA 92614			1648	
DATE MAILED: 11/17/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/817,591

Applicant(s)

SALLBERG ET AL.

Examiner

Bao Qun Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 36-65 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. A method for enhancing an immune response comprising the step of administering a composition comprising a nucleic acid molecule encoding an HCV antigen and ribavirin into a subject; classified in class 424, subclass 93.1 and subclass 228.1.
 - II. A method for enhancing an immune response comprising the step of administering a composition comprising a nucleic acid molecule encoding an HBV antigen and ribavirin into a subject, classified in class 424, subclass 93.1 and subclass 227.1.
 - III. A method for enhancing an immune response comprising the step of administering a composition comprising a nucleic acid molecule encoding an HAV antigen and ribavirin into said subject, classified in class 424, subclass 93.1 and 226.1.
2. Claims 36-38, 42-53 and 57-65 are link(s) inventions groups I-II and III. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 36-37, 42-53 and 57-65. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.
3. **The inventions are distinct, each from the other because of the following reasons:**

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4. Inventions of Group I and group II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of groups I-II are patentable distinctive methods in that each of them comprises different steps and uses structurally different composition, e.g. the method of group I comprises steps of identifying a subject an immune response to HCV and administering said subject a composition comprising HCV antigen and ribavirine, which is differs from group II that comprises steps of identifying a subject an immune response to HBV and administering said subject a composition comprising HBV antigen and ribavirine. The distinctness of the inventions are also shown by their different shearing requirements because the searching group I is related to an HCV antigen and an immune response against HCV, whereas the searching for group II is related to the HBV and an HBV immune response. The determination of the patentability of group I cannot be determined by the search of group II or vice versa

5. Inventions of Group I and group III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of groups I and III are patentable distinctive methods in that each of them comprises different steps and uses structurally different composition, e.g. the method of group I comprises steps of identifying a subject an immune response to HCV and administering said subject a composition comprising HCV antigen and ribavirine, which is differs from group III comprises steps of identifying a subject an immune response to HAV and administering said subject a composition comprising HAV antigen and ribavirine. The distinctness of the inventions are also shown by their different shearing requirements because the searching group I is related to HCV antigen and an immune response against HCV, whereas the searching for group III is related to the HAV and an HAV immune response. The determination of the patentability of group I cannot be determined by the search of group III or vice versa.

6. Inventions of Group II and group III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of groups II and III are patentable distinctive methods in that

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each of them comprises different steps and uses structurally different composition, e.g. the method of group II comprises steps of identifying a subject an immune response to HBV and administering said subject a composition comprising HBV antigen and ribavirine, which is different from group III that comprises steps of identifying an humoral immune response to HAV and administering said subject a composition comprising an HAV antigen and ribavirine. The distinctness of the inventions are also shown by their different shearing requirements because the searching group II is related to an HBV antigen and an immune response against HBV, whereas the searching for group III is related to the HAV and an HAV immune response. The determination of the patentability of group II cannot be determined by the search of group III or vice versa.

7. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II or group III, restriction for examination purposes as indicated is proper.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Baoqun Li
Bao Qun Li

11/11/2005